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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,633	12/27/2001	Timothy Caspar	BB-1386USPCT	1132

23906 7590 10/20/2004

E I DU PONT DE NEMOURS AND COMPANY  
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BARLEY MILL PLAZA 25/1128  
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WILMINGTON, DE 19805

EXAMINER

BUI, PHUONG T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/019,633	CASPAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Phuong T. Bui	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The Office acknowledges the receipt of Applicant's amendment filed July 29, 2004. Claims 25-37 are pending and are examined in the instant application. All previous rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made FINAL.

### ***Drawings***

2. As stated in the previous Office action, Applicant is required to amend the Brief Description of the Drawings to reflect the new figure designations in the new drawings.

### **Claim Rejections - 35 USC § 112, first paragraph**

3. Claims 25-27 and 30-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 or a DNA sequence encoding SEQ ID NO:2, does not reasonably provide enablement for sequences having 85-95% sequence identity to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This rejection is maintained for reasons of record. Applicant traverses as part of the utility rejection that point mutations in the conserved mid and carboxy terminal regions of human AMP deaminase I revealed sites that are important for catalytic activity and sites which might tolerate substitutions; conserved sequence motifs in human AMP deaminase I have been identified; yeast and human share 38% and 48% sequence identity with SEQ ID NO:2; the N-terminal regions show a high degree of variability among corn, yeast and

Art Unit: 1638

human; and deletion of 192 amino acids from the N-terminus of the yeast enzyme does not affect enzymatic activity (not true for rat).

Applicant's traversals have been carefully considered but are unpersuasive for the following reasons. While a skilled artisan can readily make changes to the sequence encoding SEQ ID NO:10 within the 85-95% sequence identity limitation, the artisan needs guidance as to what changes in which region(s) would tolerate such changes without destroying enzymatic activity. As indicated in the previous Office action, the state of the art teaches a single mutation can dissociate heparin receptor-binding activities; and four amino acid substitutions can convert a desaturase to a hydroxylase. The breadth of the claims encompasses unspecified base deletions, additions, substitutions, and combinations thereof while retaining enzymatic activity. Even though Applicant argues that the prior teaches certain substitutions in conserved regions are tolerated while others are not, it is unclear what amino acid positions in human AMP deaminase I would correspond with Applicant's corn sequence. The human AMP deaminase I and SEQ ID NO:2 only share 42.3% sequence identity, (not 48% as indicated by Applicant; see Table 5, p. 24) and there is no evidence they are the same length, or a position on one sequence would be the same position on the other sequence. It is noted that SEQ ID NO:2 is only a partial protein, and thus a complete protein sequence is likely to have less than 42.3% sequence identity, as the N terminus has been shown to be highly variable. It is further noted that the scope of the claims is not limited to the few substitutions in certain regions of the gene, but any addition, deletion, substitution and combinations thereof in any region of SEQ ID NO:2 within the

Art Unit: 1638

85-95% sequence identity—which the limited teachings of the prior art does not address. A sequence comprising 578 amino acids at 85% sequence identity with SEQ ID NO:2 would have 87 unspecified mutations or deletions at the amino acid level, and would have less than 85% sequence identity to the nucleic acid sequence of SEQ ID NO:1 given the degeneracy of the genetic codon. With regard to the Applicant's traversal that the first 192 amino acids at the N-terminus of yeast is not necessary for enzyme activity, this traversal also fails to persuade because, again, not know how much of the full-length protein containing SEQ ID NO:2 is missing, it is possible that deleting 192 amino acids from SEQ ID NO:2 would ablate enzyme activity. Also, it should be noted that the yeast sequence only shares 38% sequence identity with Applicant's corn sequence. Thus, it is unclear how much of the prior art teachings in yeast would be applicable to corn, as N-terminal deletions in the rat enzyme has a different effect than for yeast. It is unpredictable whether N-terminal deletions in corn would be more like yeast, rat, or unlike either one. Accordingly, the claimed invention is not enabled as commensurate in scope with the claims.

4. Claims 25-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record. The first written description issue is with regard to the "comprising" language as applicable to claims 25-37. Applicant discloses a partial open reading frame but the

Art Unit: 1638

"comprising" language encompasses the entire gene sequence. Applicant's traversal as part of the utility rejection which may be applicable here is the deletion of the 192 amino acids at the N-terminal region in yeast does not affect enzyme activity. This traversal fails to persuade because the Office is not questioning whether SEQ ID NO:2 has enzyme activity, but whether the disclosure of a partial sequence provides adequate description of the structure of the complete gene sequence. Since there is no determination that can be made from SEQ ID NO:2 that would allow one skilled in the art to predict the structure of the missing portion, the complete gene sequence cannot be adequately described. Accordingly, the claimed invention as reading on the entire gene lacks adequate written description. Amending "comprising" to "consisting" would obviate this written description issue.

With regard to the second written description issue as applied to claims having less than 100% sequence identity with SEQ ID NO:2 (claims 25-27 and 30-37), Applicant traverses, alleging the specification discloses a representative number of AMP deaminases with at least 85% sequence identity to SEQ ID NO:2. The specification also discloses alterations that are not expected to alter functionality (p. 6, lines 3-16).

Applicant's traversals are unpersuasive for the following reasons. First of all, Applicant does not indicate which AMP deaminases in the specification has at least 85% sequence identity with SEQ ID NO:2, as all sequence identities disclosed are in comparison with prior art sequences only. Secondly, while one skilled in the art can generate a population of sequences having 85-95% sequence identity with SEQ ID

Art Unit: 1638

NO:2, the 85-95% would likely encompass unknown and undiscovered AMP deaminases from other plants and animals which Applicant is not in possession of and hence should not be entitled to. Thirdly, given the diverse sources of AMP deaminases, and the significant difference in sequence identities among them, the disclosure of SEQ ID NO:2 isolated from a single corn plant does not allow one skilled in the art to predictably determine the structures of allelic mutants and variants of other corn AMP deaminases, AMP deaminases from other plants, and AMP deaminases from a non-plant source. With regard to Applicant's traversal that the specification discloses alterations in nucleotide sequence that are not expected to alter functionality, p. 6, lines 3-16 only gives general guidance as to what conservative amino acid substitutions one can make on a typical protein and still retain protein function. It does not address which sequences would be representative of the AMP deaminases that would be within 85-95% sequence identity with SEQ ID NO:2. Accordingly, the claimed invention lacks adequate description under current written description guidelines.

#### ***Remarks***

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


Art Unit: 1638

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Phuong T. Bui  
Primary Examiner  
Art Unit 1638  
10/13/04

9/22/04